



3150 NW 107<sup>th</sup> Avenue Miami FL 33172  
Tel: 305.599.7174  
Fax: 305.592.4621

K132153

## 510(k) Summary - SafeTouch PSV winged Infusion Set with/without filter

### 807.92(a)(1)

Applicant: Nipro Medical Corporation  
3150 NW 107<sup>th</sup> Ave. Doral FL 33172  
Establishment Reg.: 1056186  
Contact Person: Jessica Oswald-McLeod  
Regulatory Affairs Specialist

DEC 05 2013

Date of summary preparation: June 24, 2013

### 807.92(a)(2)

Trade Name: SafeTouch PSV winged Infusion Set with/without filter  
Common Name: Safety Scalp Vein Set  
Classification Name: catheter, intravascular, therapeutic, short-term less than 30 days  
Regulation Number: 21 CFR 880.5200  
Panel: 80  
Product Code: FOZ

### 807.92(a)(3)

Legally marketed substantial equivalent device:  
K113429 – SafeTouch PSV Winged Infusion Set with or without filter

### 807.92(a)(4)

Description of device:  
The SafeTouch PSV winged Infusion Set with/without filter consists of a winged needle (25 gauge x 3/4 inch) with an integrated safety mechanism connected to PVC tubing and a female luer connector with cap. An optional filter has been added to prevent the flow of particulate matter.

### 807.92(a)(5)

Indications for Use:  
This device is intended to be used for insertion into a patient's vascular system for single use as an indwelling device to administer fluids intravenously. Secondly it is designed with an active sharp feature that requires physical action by the clinician to prevent accidental needlesticks.

### 807.92(a)(6)

Comparison of technological characteristics:  
The Nipro SafeTouch Scalp Vein Set with/without filter is identical to the predicate device, in all aspects except the indications for use. We have removed the indication of blood sampling.

### 807.92(b)(1)

Non-clinical tests submitted:  
Performance testing was conducted to verify that the device is safe and effective for its intended use. Those tests include appearance, dimensional, package integrity testing and functional testing to include: Penetration force (puncture resistance testing), Pull force of

connections, Safety Mechanism Deactivation force, Needle Clogging Test, Leakage of product, Luer Cap Separation, Connector Taper Leakage, Internal/external surface of cannula, Cannula Elasticity, Cannula Bending Strength and Product Air Tightness. The results and conclusions of these tests are included in this submission.

807.92(b)(2)

Clinical tests submitted:

Substantial equivalence was proven through bench testing. No clinical testing was required or performed in support of this 510k submission.

807.92(b)(3)

Conclusions drawn from non-clinical and clinical tests:

The results of the performance testing and the comparison of technological characteristics with the predicate device demonstrate that the SafeTouch PSV performs equivalent to the predicate device and is safe and effective when used as intended.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center - WO66-G609  
Silver Spring, MD 20993-0002

December 5, 2013

Nipro Medical Corporation  
Ms. Jessica Oswald-McLeod  
Regulatory Affairs Specialist  
3150 NW 107<sup>th</sup> Avenue  
Miami, FL 33172

Re: K132153

Trade/Device Name: SafeTouch PSV winged Infusion Set with/without filter

Regulation Number: 21 CFR 880.5200

Regulation Name: Intravascular Catheter

Regulatory Class: II

Product Code: FOZ

Dated: November 1, 2013

Received: November 6, 2013

Dear Ms. Oswald-McLeod:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

**Kwame O.  
Ulmer -S**

for

Erin I. Keith, M.S.  
Acting Director  
Division of Anesthesiology, General Hospital,  
Respiratory, Infection Control and  
Dental Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

### Indications for Use

510(k) Number (if known)  
K132153

Device Name  
SafeTouch PSV winged Infusion Set with/without filter

Indications for Use (Describe)

The SafeTouch PSV Winged Infusion Set with/without filter is intended to be used for insertion into a patient's vascular system for single use as an indwelling device to administer fluids intravenously. Secondly it is designed with an active sharp feature that requires physical action by the clinician to prevent accidental needlesticks.

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

Digitally signed by Richard C.  
Chapman

Date: 2013.12.04 17:28:59 -05'00'